127

No. 08-1202

In The
Supreme Court of the United States

IMS HEALTH, INC. AND VERISPAN LLC,

Petitioners,

vs.

KELLY M. AYOTTE, AS ATTORNEY GENERAL OF THE STATE OF NEW HAMPSHIRE,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

BRIEF OF *AMICI CURIAE* THE CENTER FOR DEMOCRACY AND TECHNOLOGY, THE GENETIC ALLIANCE, THE PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, MARK FRISSE, AND SARA ROSENBAUM IN SUPPORT OF PETITIONERS

GREGORY A. CLARICK*
WILLIAM BERNSTEIN
ARUNABHA BHOUMIK
MANATT, PHELPS & PHILLIPS LLP
**Counsel of Record*
7 Times Square
New York, NY 10036
(212) 790-4500
Attorneys for Amici Curiae

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

OTHER AUTHORITIES

TABLE OF AUTHORITIES – Continued

CONSTITUTION

BRIEF OF THE CENTER FOR DEMOCRACY AND TECHNOLOGY, THE GENETIC ALLIANCE, THE PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, MARK FRISSE, AND SARA ROSENBAUM AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

With the joint written consent of the parties, the Center for Democracy and Technology, The Genetic Alliance, The Pharmaceutical Care Management Association, Mark Frisse, and Sara Rosenbaum respectfully submit this brief as *amici curiae*.[1]

INTERESTS OF *AMICI CURIAE*

The Center for Democracy and Technology ("CDT") is a non-profit Internet and technology advocacy organization which promotes public policies that preserve privacy and enhance civil liberties in the digital age. As information technology is increasingly used to support the exchange of medical records and other health information, CDT, through its Health Privacy Project, champions comprehensive

[1] *Amici curiae* and their counsel authored this brief in whole and no person or entity other than *amici* or its counsel has made a monetary contribution to the preparation or submission of this brief.

The parties were notified ten days prior to the due date of this brief of the intention to file. The parties have consented to the filing of this brief.

privacy and security policies to protect health data. CDT promotes its positions through public policy advocacy, public education, and litigation, as well as through the development of industry best practices and technology standards. CDT plays an instrumental role in safeguarding consumer privacy on the Internet. Recognizing that a networked health care system can lead to improved health care quality, reduced costs, and empowered consumers, CDT is using its experience to shape workable privacy solutions for a health care system characterized by electronic health information exchange.

Genetic Alliance transforms health through genetics, promoting an environment of openness centered on the health of individuals, families, and communities. Genetic Alliance brings together diverse stakeholders that create novel partnerships in advocacy; integrates individual, family, and community perspectives to improve health systems; and revolutionizes access to information to enable translation of research into services and individualized decision making.

The Pharmaceutical Care Management Association[2] ("PCMA") is the national association

---

[2] PCMA's members include the following: Aetna Inc.; Caremark Inc., a wholly-owned subsidiary of CVS/Caremark Corporation; CIGNA Health Corporation; Prime Therapeutics LLC; Express Scripts, Inc.; MC-21 Corporation; Medco Health Solutions, Inc.; RxSolutions, Inc. d/b/a Prescription Solutions, a wholly-owned subsidiary of PacifiCare Health Systems, LLC,

(Continued on following page)

representing pharmacy benefit managers (PBMs), which administer prescription drug benefits for more than 210 million Americans with health care coverage. PBMs work to drive down the cost of prescription drugs through proven cost-containment tools, including negotiating with drug manufacturers to obtain rebates on plan members' drug purchases; establishing networks of both retail and mail-order pharmacies to allow consumers access to discount drugs; and administering "drug utilization review" programs designed to monitor and deter purchases of dangerous drug combinations and questionable doses. PBMs also have been at the forefront in advancing cutting-edge technologies such as electronic prescribing, which provides physicians with clinical and cost information on prescription options that allows them to better counsel consumers regarding which medications are the safest and most affordable choices.

Mark Frisse is a physician and Accenture Professor of Biomedical Informatics at Vanderbilt University. Working on a five-year project funded by AHRQ and the State of Tennessee, Dr. Frisse was a

---

which in turn is a wholly-owned subsidiary of UnitedHealth Group Incorporated; Wellpoint Pharmacy Management (a d/b/a for Professional Claims Services, Inc.) and Anthem Prescription Management, LLC, both of which are wholly-owned subsidiaries of Wellpoint, Inc.; US Scripts, Inc.; and Scriptrax, part of Novant Health – a not-for-profit health care system.

leader in efforts to create a regional health information exchange involving all major providers in the Memphis area. The exchange has comprehensive data sharing agreements and supports care for over 750,000 people; it has been in operation for over two years. In addition, Dr. Frisse was involved in a large-scale data integration project in the mid-1990s that provided drug interaction alerts to pharmacists at the BJC Health System in St. Louis. He has also led workshops and authored comprehensive reports on privacy, confidentiality, and health information exchange.

Sara Rosenbaum is the Harold and Jane Hirsh Professor of Health Law and Policy and chair of the Department of Health Policy at the George Washington University School of Public Health Services. A leader in health policy, with a particular focus on health care access for medically underserved populations, Professor Rosenbaum is known nationally for her work on health insurance, national health reform, and health care access. For five years Professor Rosenbaum has led a series of studies for the United States Department of Health and Human Services that examine health information technology adoption among physicians and hospitals. She has written extensively on numerous aspects of health law, including health information law, and is a co-author of Law and the American Health Care System (Foundation Press).

The New Hampshire law at issue in this case is directly at odds with the policy objectives of *amici*. In

the service of privacy interests that do not exist, the law will impede efforts to reform our health care system and improve the quality and efficiency of health care provided to patients and populations. Therefore, *amici* write to assist the Court in analyzing the legal and public policy issues that warrant this Court's review of the decision of the Circuit Court of Appeals for the First Circuit.

SUMMARY OF ARGUMENT

1. The Court should grant the petition because the Prescription Information Law does not implicate any legitimate privacy interest. The New Hampshire Legislature and New Hampshire Attorney General have sought to justify the Prescription Information Law on the grounds that New Hampshire has an interest in protecting the privacy of both patients and prescribers, and that this interest requires limiting the exchange of prescription information. The Prescription Information Law, however, does not protect any legitimate privacy interest. Physicians have no privacy interest in their prescribing practices. Such practices are consistently revealed to, and reviewed by, numerous third-parties. Nor is patient privacy at issue here. The Prescription Information Law regulates "de-identified" patient information that does not implicate patient privacy. Further, tremendous public health benefits are associated with the transfer and use of de-identified health care information. Review by this Court is

therefore critical to facilitate the national interest in the use of health care information where, as here, it does not implicate any legitimate privacy interest.

2. The Court should grant the petition because the Prescription Information Law and copycat legislation in other states threaten to strangle efforts to use health care information technology to improve patient care and public health. Information technology has made it easier than ever to collect, exchange, aggregate, analyze, and communicate health information electronically. This has enormous potential benefits, including improved health outcomes, better quality of care, and lower costs. Indeed, President Obama recognized this potential when his administration authorized $36 billion in federal stimulus funds to encourage adoption of health IT tools. But the New Hampshire Prescription Information Law – with its broad undefined prohibitions, and amorphous exceptions – threatens to undermine this important national trend.

ARGUMENT

I.

THIS COURT SHOULD GRANT THE PETITION FOR A WRIT OF CERTIORARI BECAUSE PATIENTS AND HEALTH CARE PROVIDERS DO NOT HAVE ANY PRIVACY INTERESTS IN THE INFORMATION THAT THE PRESCRIPTION INFORMATION LAW PROTECTS

The legislative record is replete with references to the supposed "privacy" interests that the Prescription Information Law would protect. Representative Cindy Rosenwald, one of the statute's co-sponsors, noted that the statute "will protect privacy . . . by prohibiting the sale or use of individual patient or prescriber identity."[3] Further, in defending the statute below, the New Hampshire Attorney General justified the law on the grounds that it protects both patient and prescriber policy.

These "privacy" considerations are phantoms. The Prescription Information Law does not protect any legitimate privacy interest.

First, there is no physician privacy to protect because physicians have no expectation of privacy in

---

[3] *See* An Act Requiring Certain Persons To Keep the Contents of Prescriptions Confidential: Hearing on H.B. 1346 Before the S. Comm. on Exec. Departments & Administration, 159th Sess. Gen. Ct. 1 (N.H. 2006) (statement of Rep. Cindy Rosenwald, Member, House of Representatives).

their prescribing practices. As the District Court noted below, the provisions challenged here relate to the professional practice of prescribers, not personal information. *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163, 179 n.13 (D.N.H. 2007). Thus, health care providers, who work in a "closely regulated" industry, cannot claim *any* expectation of privacy over their professional practices because "prescriber-identifiable data is routinely disclosed to patients, pharmacies, insurance companies, medical review committees, and government agencies." *Id.* (citing *New York v. Burger*, 482 U.S. 691, 702, 107 S. Ct. 2636, 96 L. Ed. 2d 601 (1987)); *see also Marshall v. Barlow's, Inc.*, 436 U.S. 307, 313, 98 S. Ct. 1816, 56 L. Ed. 2d 305 (1978) ("Certain industries have such a history of government oversight that no reasonable expectation of privacy could exist . . . ".) (internal citation omitted).

Second, the Prescription Information Law does not implicate patient privacy. While it purports to protect privacy interests, the statute regulates patient *de-identified* information. At the federal level, the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d et seq. ("HIPAA"), provides rigorous standards for de-identifying information, which involve either certification by a statistician that the information has been de-identified or the removal of specific identifiers including name, social security number, medical record number, and address.

HIPAA also sets national standards for the use and disclosure of Americans' *identifiable* health

information. Specifically, the HIPAA Privacy Rule regulates the use and disclosure of Protected Health Information ("PHI"), i.e., information concerning health status, provision of health care, or payment for health care that identifies an individual. HIPAA recognizes the need to place clear, enforceable parameters around the use of such identifiable information. In contrast, HIPAA expressly does *not* restrict the use or disclosure of de-identified health information, which is sufficiently stripped of patient identifiers that its use and disclosure raises no privacy risk to patients.

In making this distinction, HIPAA highlights the substantial public health benefits of permitting broad access to de-identified data. As the Department of Health and Human Services noted in its commentary supporting HIPAA:

> Large data sets of de-identified information can be used for innumerable purposes that are vital to improving the efficiency and effectiveness of health care delivery, such as epidemiological studies, comparisons of cost, quality or specific outcomes across providers or payers, studies of incidence or prevalence of disease across populations, areas or time, and studies of access to care or differing use patterns across populations, areas or time.

Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59918, 59946 (proposed Nov. 3, 1999).

These benefits are not just theoretical. Researchers and government officials have, on numerous occasions, used de-identified health information to benefit the public health. The National Committee for Quality Assurance ("NCQA"), for example, uses de-identified health care information to monitor variations in quality of care. In one remarkable example, the use of de-identified health information led to more than 97% of patients who suffered heart attacks being prescribed beta-blockers to help prevent a second attack, up from only 62% in 1996. This improvement alone saved between 4,400 and 5,600 lives over the past six years. NCQA, *The State of Health Care Quality 2007* 10, 26 (2007).

Further, the risk to patient privacy as a result of transferring de-identified data under HIPAA generally arises from efforts to re-identify patients using the data. In this regard, while HIPAA privacy protections could be strengthened, this would be achieved by strengthening prohibitions against re-identification of de-identified data. But the Prescription Information Law does no such thing. Rather, the statute throws the baby out with the bathwater – prohibiting the transfer of de-identified information for *commercial* purposes – a limitation that has nothing to do with preventing re-identification of patient information.

Review of the Prescription Information Law is therefore critical to facilitate the national interest in enhancing the flow and use of health care information

where, as here, it does not implicate any legitimate privacy interest.

II.

THIS COURT SHOULD GRANT THE PETITION FOR A WRIT OF CERTIORARI BECAUSE THE NEW HAMPSHIRE STATUTE WILL STIFLE EFFORTS TO EVALUATE AND IMPROVE HEALTH CARE QUALITY THROUGH HEALTH INFORMATION TECHNOLOGY

The use of health information technology, or health IT, is one of the most important developments in modern health care. Health IT encompasses the trend in the health care sector to collect, exchange, aggregate, analyze, and communicate health information electronically. Health IT offers providers quick and reliable access to needed patient information, and thus improves care. Thus health IT is not an end unto itself, but rather is a means of improving the quality of health care.

With the advent of health information technologies like electronic health records that facilitate information sharing among providers at the point of care, we are at the tipping point when it comes to our ability to evaluate and improve provider performance, and therefore care of patients. To make health care delivery better, safer, more efficient, and less prone to medical errors, we need to know more – not less – about what physicians and other health care providers do. Much of what we need to know to

accomplish these aims can be served by using de-identified data, which can be collected, analyzed, exchanged, and communicated electronically to those who would rely on it to improve care, thanks to advances in health information technology.

The potential for health IT to improve patient care and health care quality is particularly compelling. Remarkably, more Americans die each year from preventable medical errors than from AIDS or breast cancer. Institute of Medicine, *To Err Is Human: Building a Safe Health System* (1999). Indeed, the NCQA reports between 35,000 and 75,000 avoidable deaths, and between $2.7 billion and $3.7 billion in avoidable hospital costs in the year 2006 due to unexplained variations in quality of care. NCQA, *The State of Health Care Quality 2007* 12 (2007). Further, while substantial investments have been made in clinical research and development over the last 30 years, resulting in an enormous increase in medical knowledge, a 15 to 20 year lag exists before physicians incorporate this knowledge into their care. E.A. Balas and S.A. Boren, *Managing Clinical Knowledge for Health Care Improvement,* in *IMIA Yearbook of Medical Informatics* 65-70 (2000). Health IT can reduce this lag. As the Institute of Medicine stated, "[t]o deliver care in the 21st century, the [health care] system must have a health information and communications technology infrastructure that is accessible to all patients and providers." Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001).

In recognition of both the importance of health IT to delivering quality health care and its potential economic benefits, President Obama recently included in the federal stimulus package approximately $36 billion to network the health care industry so that it can deliver high-quality efficient patient care.[4] But the President is only the most recent leader to recognize the enormous potential of health IT to bring transparency to the health care system and improve patient care. Indeed, a 2006 report noted that President Bush, both parties' congressional leaders, and nearly 40 states' governors and state legislatures had begun to pursue major health IT initiatives, to achieve greater value for health care spending. *See* eHealth Initiative, *eHealth Initiative Issue Brief: States Getting Connected: State Policy-Makers Drive Improvements in Healthcare Quality and Safety Through IT* (2006). These leaders want to use health IT to save lives, and they want patients to make health care decisions armed with information about the cost and quality of the services they are buying.

But the New Hampshire law – and others like it – threatens to undermine the access to information that will drive these reforms. While the First Circuit construed the Prescription Information Law to prohibit only the transfer of prescription information

---

[4] *See Letter dated February 13, 2009 from Congressional Budget Office to Speaker of the House of Representatives Nancy Pelosi* at Table 2, available at http://www.cbo.gov/doc.cfm?index=9989 (last viewed April 23, 2009).

used for the purposes of detailing, the language of the statute is considerably broader. Rather than directly regulating the conduct of detailers in connection with pharmaceutical company marketing efforts, the law *criminalizes* the transfer of "prescription information containing . . . prescriber-identifiable data . . . for *any commercial purpose*." The term "commercial purpose" is defined as "*any* activity that could be used to influence or even to evaluate the prescribing behavior of physicians."

Moreover, while the statute contains several exceptions, none are clearly defined. Thus, with limited, undefined, and amorphous exceptions, the law prohibits pharmacies, benefits managers, insurance companies, and the like from selling "for any commercial purpose" information about prescriptions written by New Hampshire prescribers.

Health IT is the key to facilitating the flow of information to both patients and physicians that will enable improvements in health care. But an overbroad statute, with poorly defined exceptions will have a chilling effect on the development of health IT. This effect is overwhelming when one considers that a number of other states are considering similarly broadly worded statutes, with poorly defined proscriptions, and indeterminate exceptions. Moreover, while the First Circuit read the Prescription Information Law to proscribe only the transfer of prescriber information for the purposes of detailing, there is no guarantee that other courts – including New Hampshire courts applying the law – will read

the statute the same way. Nor will other courts reviewing other states' statutes be held to the First Circuit's interpretation of the New Hampshire enactment.

The development of a national "health information superhighway" that is facilitated through health IT – an enterprise that is inherently interconnected and national in scope – will be choked if, in order to do business, companies have to wade through a morass of state statutes with unclear prohibitions and exceptions. Indeed, this Court's jurisprudence under the Commerce Clause already has recognized that where an industry is not "admitting of diversity of treatment, according to the special requirements of local conditions" a State requirement that is "out of line with the requirements of almost all the other States" may place an undue burden on interstate commerce. *See Bibb v. Navajo Freight Lines*, 359 U.S. 520, 529-30, 79 S. Ct. 962, 3 L. Ed. 2d 1003 (1959); *see also CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 88, 95 L. Ed. 2d 67, 107 S. Ct. 1637 (1987) ("This Court's recent Commerce Clause cases also have invalidated statutes that may adversely affect interstate commerce by subjecting activities to inconsistent regulations.").

Review of this case is vital. The development of health IT will improve access to health care information for patients, providers and researchers. It will save lives. The New Hampshire Prescription Information Law – and others like it – threaten to stifle the development of this technology by requiring

patients and industry to navigate a patchwork of state regulatory regimes with vague statutes regarding access to de-identified health data, and at least in the case of New Hampshire, risk *criminal* penalty should they run afoul of one of these regimes.

CONCLUSION

Review by this Court is imperative. The New Hampshire Prescription Information Law may have been the brainchild of good intentions. Still, it will impair the development of health IT and the essential use of de-identified health information to improve access to information, save lives, and reduce risks endemic to the health care system.

By justifying the statute on "privacy" grounds, the State has incorrectly presumed that prescribers have a privacy interest in their medical practices. But prescribers, who work in a highly-regulated industry, have no expectation of privacy in their medical practice, and federal law already provides rigorous standards for de-identifying patient health care information to protect patient privacy interests.

While States may provide privacy protection for patient health information that is greater than the federal floor HIPAA sets, the New Hampshire statute – which regulates *de-identified* information – simply doesn't do so. Instead, it subjects the collection of critical health data using health IT to a thicket of vague, perhaps inconsistent local regulations. Thus,

the New Hampshire Prescription Information Law – and others like it – will impair the development of the technology, leading to less access to information, and enormous public health consequences.

Respectfully submitted,

GREGORY A. CLARICK*
WILLIAM BERNSTEIN
ARUNABHA BHOUMIK
MANATT, PHELPS & PHILLIPS LLP
**Counsel of Record*
7 Times Square
New York, NY 10036
(212) 790-4500

Attorneys for Amici Curiae
The Center for Democracy and Technology,
The Genetic Alliance,
The Pharmaceutical Care Management Association,
Mark Frisse, and
Sara Rosenbaum